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10/063,722	05/08/2002	Dan L. Eaton	P3230R1C001-168	1239	
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KNOBBE, MARTENS, OLSON & BEAR, LLP 2040 MAIN STREET IRVINE, CA 92614			ROMEO, DAVID S		
			ART UNIT	PAPER NUMBER	
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			DATE MAILED: 10/19/2004		

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)				
	10/063,722	EATON ET AL.				
Office Action Summary	Examiner	Art Unit				
	David S Romeo	1647				
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply						
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status						
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·	1) Responsive to communication(s) filed on <u>03 September 2004</u> .					
2a) ☐ This action is FINAL . 2b) ☐ This action is non-final. 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is						
closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.						
Disposition of Claims						
4) Claim(s) 1-20 is/are pending in the application. 4a) Of the above claim(s) is/are withdrawn from consideration. 5) Claim(s) is/are allowed. 6) Claim(s) 1-20 is/are rejected. 7) Claim(s) is/are objected to. 8) Claim(s) are subject to restriction and/or election requirement.						
Application Papers						
9) The specification is objected to by the Examiner						
10) The drawing(s) filed on is/are: a) acce	pted or b) objected to by the E	xaminer.				
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).						
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.						
Priority under 35 U.S.C. § 119						
 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. 						
Attachment(s)						
1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 1003,0902. 4) Interview Summary (PTO-413) Paper No(s)/Mail Date 5) Notice of Informal Patent Application (PTO-152) 6) Other:						

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DETAILED ACTION

The preliminary amendment filed 09/10/2002 has been entered. Claims 1-20 are pending and being examined.

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Specification

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

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Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

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The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 1-20 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility.

The claims are directed to or encompass an isolated nucleic acid molecule encoding the amino acid sequence of SEQ ID NO: 102, an isolated nucleic acid molecule

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having a recited % identity to a nucleic acid molecule encoding the amino acid sequence of SEQ ID NO: 102 or to SEQ ID NO: 101, and an isolated nucleic acid molecule that hybridizes to an isolated nucleic acid molecule encoding the amino acid sequence of SEQ ID NO: 102 or to SEQ ID NO: 101.

The specification discloses a nucleotide sequence (SEQ ID NO: 101) of a native sequence PRO3579 cDNA, wherein SEQ ID NO: 101 is a clone designated as "DNA68862-2546" (paragraph 0128). FIG. 102 shows the amino acid sequence (SEQ ID NO: 102) derived from the coding sequence of SEQ ID NO: 101 shown in FIG. 101 (paragraph 0129). The specification discloses uses for PRO polynucleotides and polypeptides in general (paragraphs 0316-0360; pages 86-100). Example 18 (Tumor Versus Normal Differential Tissue Expression Distribution) discloses that DNA68862-2546 is more highly expressed in melanoma tumor as compared to normal skin (page 141). Identification of the differential expression of the PRO polypeptide-encoding nucleic acid in one or more tumor tissues as compared to one or more normal tissues of the same tissue type renders the molecule useful diagnostically for the determination of the presence or absence of tumor in a subject suspected of possessing a tumor as well as therapeutically as a target for the treatment of a tumor in a subject possessing such a tumor (paragraph 0491).

The PRO3579 polynucleotide appears to encode a membrane-bound protein or receptor. The present specification discloses that secreted proteins and membrane-bound proteins and receptors have widely varying activities (paragraphs 0002-0004). This finding establishes that secreted proteins and membrane-bound proteins and receptors have very diverse functions and makes it clear that classification of a protein as a secreted

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protein or a membrane-bound protein or receptor does not identify it as having a specific function. The specification provides no basis for concluding which, if any, of the varied activities of secreted proteins and membrane-bound proteins and receptors is possessed by the PRO3579 polypeptide. The examiner is aware that the present claims are drawn to a polynucleotide. However, there is no evidence that a skilled artisan would have appreciated the identification of the PRO3579 polynucleotide as encoding a membrane-bound protein or receptor, without more, would have suggested any specific patentable utility.

The disclosed uses for PRO polynucleotides and polypeptides in general (paragraphs 0316-0360) are not specific to the PRO3579 polynucleotide.

Although the specification discloses that DNA68862-2546 is more highly expressed in melanoma tumor as compared to normal skin (page 141), the specification provides no information regarding the absolute values of the differences in transcript levels and provides no information regarding level of expression, activity, or role of the PRO3579 polypeptide in cancer. The art demonstrates that increased transcript levels do not necessarily correlate with increased polypeptide levels. See Haynes (U), who studied more than 80 proteins relatively homogeneous in half-life and expression level, and found no strong correlation between protein and transcript level. For some genes, equivalent mRNA levels translated into protein abundances which varied more than 50-fold. Haynes concluded that the protein levels cannot be accurately predicted from the level of the corresponding mRNA transcript (page 1863, second paragraph, and Figure 1). Hancock (V) states that "the markers that are generated by proteomics are not always consistent with the markers that are generated from expression profiling" (full paragraph

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2). Therefore, the art indicates that transcript levels are not always correlated with protein levels.

Furthermore, the literature cautions researchers from drawing conclusions based

on small changes in transcript expression levels between normal and cancerous tissue. For example, Hu (W) analyzed 2286 genes that showed a greater than 1-fold difference in mean expression level between breast cancer samples and normal samples in a microarray (page 408, middle of right column). Hu discovered that, for genes displaying a 5-fold change or less in tumors compared to normal, there was no evidence of a correlation between altered gene expression and a known role in the disease. However, among genes with a 10-fold or more change in expression level, there was a strong and significant correlation between expression level and a published role in the disease (see discussion section).

In addition, Wang indicates that differential display is the first of many steps required in the discovery of a novel pharmacological target, especially given that the function of the factor is most likely unknown. Therefore, further action should be taken to characterize the functions of a particular gene of interest, including ... validation for the importance of the gene in disease processes. See page 279, column 2, full paragraph 1.

Finally, one skilled in the art recognizes that although structural similarity can serve to classify a protein as related to other known proteins this classification is insufficient to establish a function or biological significance for the protein because ancient duplications and rearrangements of protein-coding segments have resulted in complex gene family relationships. Duplications can be tandem or dispersed and can involve entire coding regions or modules that correspond to folded protein domains. As a

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result, gene products may acquire new specificities, altered recognition properties, or modified functions. Extreme proliferation of some families within an organism, perhaps at the expense of other families, may correspond to functional innovations during evolution. See Henikoff (Y), page 609, Abstract. Accordingly, one skilled in the art would not accept mere homology as establishing a function of protein because gene products may acquire new specificities, altered recognition properties, or modified functions. Rather, homology complements experimental data accumulated for the homologous protein in understanding the homologous protein's biological role.

Although, the presence of a protein module in a protein of interest adds potential insight into its function and guides experiments, insight into the biological function of a protein cannot be automated. However, homology can be used to guide further research. See Henikoff (Y), paragraph bridging pages 613-614, through page 614, paragraph bridging columns 1-2.

Haynes, Hancock, Hu, Wang, and Henikoff are evidence that the specification fails to disclose enough information about the invention to make its usefulness immediately apparent to those familiar with the technological field of the invention. This countervailing evidence shows that the skilled artisan would have a legitimate basis to doubt the significance of the disclosed differential expression of the PRO3579 transcript and doubt the utility of the PRO3579 polynucleotide. The skilled artisan would not know if PRO3579 polynucleotide transcript levels or PRO3579 polypeptide expression could, should, or would be upregulated, down-regulated, or unchanged in cancer. Therefore, the disclosure that DNA68862-2546 is more highly expressed in melanoma tumor as compared to normal skin (page 141) does not impute a specific, substantial, and credible

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utility to the PRO3579 polynucleotide. Based on the present disclosure, one skilled in the art would be required to carry out further research to identify or reasonably confirm a "real world" context of use for the claimed polynucleotides. Utilities that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use are not substantial utilities. Therefore, the increased transcript levels DNA68862-2546 in melanoma tumor as compared to normal skin (page 141) does not establish a substantial or real-world use for the claimed polynucleotides. Thus, the present disclosure is simply a starting point for further research and investigation into potential practical uses of the claimed polynucleotides. See Brenner v. Manson, 148 U.S.P.Q. 689 (Sus. Ct, 1966), wherein the court held that:

"The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility", "[u]nless and until a process is refined and developed to this point-where specific benefit exists in currently available form-there is insufficient justification for permitting an applicant to engross what may prove to be a broad field", and "a patent is not a hunting license", "[i]t is not a reward for the search, but compensation for its successful conclusion."

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Claims 1-20 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

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Claims 1-10, 14-20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which

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was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are directed to or encompass:

the genus of all nucleic acid molecules having a recited % identity to a nucleic acid molecule within the genus of all nucleic acid molecules encoding the amino acid sequence of SEQ ID NO: 102,

the genus of all nucleic acid molecules having a recited % identity to SEQ ID NO: 101,

the genus of all nucleic acid molecules encoding the amino acid sequence of SEQ ID NO: 102,

the genus of all nucleic acid molecules that hybridize to a nucleic acid molecule within the genus of all nucleic acid molecules encoding the amino acid sequence of SEQ ID NO: 102, and

the genus of all nucleic acid molecules that hybridize to SEQ ID NO: 101. There are no functional limitations in the claims. The claims are broad because they do not require the claimed polypeptide to be identical to the disclosed PRO3579 polynucleotide and because the claims have no functional limitation.

The present specification discloses a nucleotide sequence (SEQ ID NO: 101) of a

20 native sequence PRO3579 cDNA, wherein SEQ ID NO: 101 is a clone designated as

"DNA68862-2546" (paragraph 0128). FIG. 102 shows the amino acid sequence (SEQ ID NO: 102) derived from the coding sequence of SEQ ID NO: 101 shown in FIG. 101

(paragraph 0129). The specification discloses uses for PRO polynucleotides and

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polypeptides in general (paragraphs 0316-0360; pages 86-100). Example 18 (Tumor Versus Normal Differential Tissue Expression Distribution) discloses that DNA68862-2546 is more highly expressed in melanoma tumor as compared to normal skin (page 141). Identification of the differential expression of the PRO polypeptide-encoding nucleic acid in one or more tumor tissues as compared to one or more normal tissues of the same tissue type renders the molecule useful diagnostically for the determination of the presence or absence of tumor in a subject suspected of possessing a tumor as well as therapeutically as a target for the treatment of a tumor in a subject possessing such a tumor (paragraph 0491).

The first paragraph of 35 U.S.C. 112; that paragraph requires that scope of claims must bear a reasonable correlation to scope of enablement provided by specification to persons of ordinary skill in the art; in cases involving predictable factors, such as mechanical or electrical elements, a single embodiment provides broad enablement in the sense that, once imagined, other embodiments can be made without difficulty and their performance characteristics predicted by resort to known scientific laws; in cases involving unpredictable factors, such as most chemical reactions and physiological activity, scope of enablement varies inversely with degree of unpredictability of factors involved.

The differential expression of the PRO3579 transcript was generated using PCR

primers that measured amplification of the coding region of SEQ ID NO: 101. However,
the claims are broadly drawn to variants of SEQ ID NO: 101, including fragments,
degenerate variants, and hybridizing nucleic acid molecules which have substitutions
relative to SEQ ID NO: 101. One skilled in the art would expect that such variant

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sequences would lose their specificity as probes for the target sequence. The specification does not provide any information regarding the occurrence of these variant polynucleotides in nature and it is unpredictable which of those sequences, other than the native SEQ ID NO: 101 sequence, would be a native PRO polynucleotide encoding a native PRO polypeptide. Only a limited number of polynucleotides encompassed by the 5 genus of all nucleic acid molecules encoding the amino acid sequence of SEQ ID NO: 102 occur in nature. The specification only presents one such naturally occurring nucleic acid molecule, SEQ ID NO: 101. The only obvious use of the degenerate and/or variant polynucleotides is in the production of the encoded polypeptide. However, the specification does not teach how to use the PRO3579 polypeptide or variants thereof, and 10 there is no functional limitation in the claims. In the absence of this information the skilled artisan is left to an unduly extensive amount of random trial and error experimentation, wherein PRO3579 degenerate and variant polynucleotides are randomly made and screened for a useful activity. Furthermore, there are no working examples of polynucleotides that are not identical to SEQ ID NO: 101. The examiner is aware that working examples are not required. Lack of a working example, however, is a factor to be considered, especially in cases involving an unpredictable and undeveloped art. The instant specification provides no working examples and no guidance that would permit an artisan to practice the invention commensurate with the scope of the instant claims. While a specification need not disclose what is well known in the art, that rule does not excuse an applicant from providing a complete disclosure. It is the specification, not the knowledge of one skilled in the art, that must supply the novel aspects of an invention in order to constitute adequate enablement. To practice the instant invention in a manner

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consistent with the breadth of the claims would not require just a repetition of work that is described in the instant application but a substantial inventive contribution on the part of a practitioner. It is this additional characterization of that single disclosed, naturally occurring polynucleotide that constitutes undue experimentation.

The claim encompasses an unreasonable number of polynucleotides encoding inoperative polypeptides, which the skilled artisan would not know how to use. The skilled artisan would not know how to use the full scope of the degenerate and/or variant polynucleotides on the basis of teachings in the present specification. Therefore, the scope of the claimed polynucleotides is not representative of the scope of enablement provided by the specification. Therefore, even if Applicant were to establish that the differential expression of the PRO3579 transcript provides utility and enablement for the coding region of SEQ ID NO: 101, the utility and enablement would not convey to the claimed variant polynucleotides and fragments outside the coding region.

For these reasons, which include the complexity and unpredictability of the nature of the invention, the one limited working example of the PRO3579 polynucleotide SEQ ID NO: 101, the lack of direction or guidance for using polynucleotides encoding polypeptides that are not identical to the PRO3579 polypeptide SEQ ID NO: 102, and the breadth of the claims for structure without function, it would require undue experimentation to use the invention commensurate in scope with the claims.

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Claims 1-5, 14-20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one

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skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to polynucleotides encoding polypeptides having at least 80%, 85%, 90%, 95% or 99% sequence identity with a polynucleotide encoding SEQ ID NO: 102 or with SEQ ID NO: 101 and to polynucleotides that hybridize to polynucleotides encoding SEQ ID NO: 102 or that hybridize to SEQ ID NO: 101. The claims do not require that the polynucleotides possess any particular biological activity, nor any particular conserved structure, or other disclosed distinguishing feature. Thus, the claims are drawn to a genus of polynucleotides that is defined only by some level of sequence identity that is either expressed or implied by the hybridization language.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of compete or partial structure, physical and/or chemical properties, functional characteristics,

15 structure/function correlation, methods of making the claimed product, or any combination thereof. In this case, the only factor present in the claim is a partial structure in the form of a recitation of percent identity or hybridization. There is not even identification of any particular portion of the structure that must be conserved.

Accordingly, in the absence of sufficient recitation of distinguishing identifying

20 characteristics, the specification does not provide adequate written description of the claimed genus.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought,

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he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116). As discussed above, the skilled artisan cannot envision the detailed chemical structure of the encompassed genus of polynucleotides, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See Fiers v. Revel, 25 USPQ2d 1601 at 1606 (CAFC 1993) and Amgen Inc. v. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016.

One cannot describe what one has not conceived. See Fiddes v. Baird, 30 USPQ2d 1481 at 1483. In Fiddes, claims directed to mammalian FGFs were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

Therefore, only isolated polynucleotides encoding polypeptides comprising the amino acid sequence set forth in SEQ ID NO: 102, but not the full breadth of the claim meets the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

Claims 1-6, 9, 10, 14-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter

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which applicant regards as the invention. Claims 1-6, 9, 10, 14-20 are indefinite over the recitation of "the extracellular domain" and "the extracellular domain ... lacking its associated signal sequence" because Figure 102 discloses that SEQ ID NO: 102 possesses several transmembrane domains, and, thus, a corresponding number of extracellular domains, depending on how the polypeptide is arranged in the membrane. Thus, there is no one, single extracellular domain as is implied by the phrase "the extracellular domain." It is unclear how the polypeptide is arranged in the membrane. Thus, it is unclear which segment(s) is an extracellular domain. It is also unclear if all the extracellular domains are to be collectively construed as "the extracellular domain" or if only one extracellular domain from amongst several extracellular domains is intended. Further, an extracellular domain bound by two transmembrane domains would not have an "associated signal sequence." Thus, it is unclear how to construe the phrase "the extracellular domain ... lacking its associated signal sequence." The metes and bounds are not clearly set forth.

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Claim 15 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 15 is indefinite over the recitation of "stringent conditions" because

stringency varies according to the hybridization conditions and the particular hybrid
under study. The specification fails to limit the definition of "stringent conditions." The
metes and bounds are not clearly set forth.

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Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(f) he did not himself invent the subject matter sought to be patented.

Claims 1-17 are rejected under 35 U.S.C. 102(f) because the applicant did not invent the claimed subject matter. In U.S. Application No. 60/170,262 it is disclosed that Applicants purchased Incyte EST clone no. 2377329 and the cDNA insert was obtained and sequenced. The sequence of this cDNA insert is shown in Figure 1 and is designated as DNA68862-2546. Figure 1 in U.S. Application No. 60/170,262 appears to be identical to figure 101 of the present application. Furthermore, the present application designates SEQ ID NO: 101 as "DNA68862-2546" (paragraph 0128).

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Conclusion

No claims are allowable.

ANY INQUIRY CONCERNING THIS COMMUNICATION OR EARLIER COMMUNICATIONS FROM THE EXAMINER SHOULD BE DIRECTED TO DAVID S. ROMEO WHOSE TELEPHONE NUMBER IS (571) 272-0890. THE EXAMINER CAN NORMALLY BE REACHED ON MONDAY THROUGH FRIDAY FROM 7:30 A.M. TO 4:00 P.M. IF ATTEMPTS TO REACH THE EXAMINER BY TELEPHONE ARE UNSUCCESSFUL, THE EXAMINER'S SUPERVISOR, BRENDA BRUMBACK, CAN BE REACHED ON (571)272-0961.

IF SUBMITTING OFFICIAL CORRESPONDENCE BY FAX, APPLICANTS ARE ENCOURAGED TO SUBMIT OFFICIAL CORRESPONDENCE TO THE FOLLOWING TC 1600 BEFORE AND AFTER FINAL RIGHTFAX NUMBERS:

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ANY INQUIRY OF A GENERAL NATURE OR RELATING TO THE STATUS OF THIS APPLICATION OR PROCEEDING SHOULD BE DIRECTED TO THE GROUP RECEPTIONIST WHOSE TELEPHONE NUMBER IS (703) 308-0196.

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DAVID ROMEO

PRIMARY EXAMINER ART UNIT 1647

OCTOBER 13, 2004